

# ChemReg®

INTERNATIONAL, LLC

466788-00

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BRUCE D. RIGGLE, PH.D.

October 13, 2005

Via Hand Delivery

U.S. Environmental Protection Agency  
Office of Pesticide Programs (7404C - APPLX(REG FEE))  
Registration Division  
Crystal Mall #2  
1810 Bell Street  
Arlington, Virginia 22202  
Attention: Carl Grable

Ref: Sodium Chlorite Registration for Field Treated Wheat, Barley, and Oats  
Formulator's Exemption / Repack of EPA Reg. No. 5382-43  
Petition for an Exemption from the Requirement of a Tolerance  
Reduced Risk Use Classification Request  
Proposed PRIA Fee Code: R18

Biox Plus EPA No. 80556-XXX

Dear Carl:

ChemReg International LLC (ChemReg) is submitting on behalf of Bi-oxide Crop Science (Bi-oxide) for a registration and an exemption from the requirement of a tolerance for the field use of sodium chlorite on wheat, barley, and oats. The retail product will be named Biox Plus. This follows the pre-registration meeting of November 16, 2004 with the Registration Division (RD) of the U.S. Environmental Protection Agency (EPA). In that meeting, ChemReg informed RD that Bi-oxide would supply the necessary data for a Formulator's Exemption Registration (a repack) for sodium chlorite and that Bi-oxide also wished to expand the existing use pattern for sodium chlorite to include field applications to wheat, barley, and oats and that the EPA accepted terminal residue is sodium chloride (table salt). Also in that meeting ChemReg requested that RD accept data waiver requests in place of actual GLP Guideline Studies. RD

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Expertise in Toxicology, Residue and Product Chemistry, Environmental Fate, Efficacy, Registration Strategies and Implementation, Regulatory Compliance, Label Development, Exposure and Risk Assessments, Data Citation and Compensation, Study Design and Monitoring.

agreed to this request based on the fact that the chemistry is well known within the Agency. RD did however stipulate that the waivers would have to be detailed and would have to address the basic requirements for field use as not covered in the current Vulcan Chemical registered use pattern. RD also agreed to ChemReg's request that the detailed waiver requests would be in a report format as specified in PR Notice 86-5 and would be assigned MRID numbers.

The Agency and the U.S. Food and Drug Administration (FDA) have already taken the following actions regarding crop and food uses of sodium chlorite and chlorine dioxide (the Agency accepts these two chemicals to be one and the same). Sodium chlorite is exempt from the requirement of a tolerance when used as a seed-soak treatment in the growing of the raw agricultural commodities crop group *Brassica* (cole) leafy vegetables and radishes (40 CFR §180.1070). The Agency (Brennis, Antimicrobial Division, August 5, 2003) approved the post-harvest use of chlorine dioxide, as generated from sodium chlorite, on stored potatoes at rates of up to 400 ppm. EPA exempted sodium chlorite and chlorine dioxide from the requirement of a tolerance and stated that "After careful evaluation by our scientific staff it was determined that it is unlikely that there would be a residue of chlorine dioxide on the potatoes, so no food tolerance is required". It should be noted that no restrictions were placed on potato culls from this post harvest use and that potato culls are a cattle-feed item. FDA approved the use of chlorine dioxide on cereal flours (including wheat and barley [malted flour]) in an unspecified quantity not more than sufficient for bleaching purposes (21 CFR §137.105). This approved use would potentially leave residues of sodium chlorite, how experience with this chemistry has demonstrated that in the presence of organic matter, chlorine dioxide will be rapidly reduced to sodium chloride.

Again, Bi-oxide is requesting a Formulator's Exemption registration and Bi-oxide will rely on Vulcan Chemical (EPA Reg. No. 5382-43) for product chemistry (40 CFR §158.190), wildlife and aquatic organisms data (40 CFR §158.490), and toxicology data (40 CFR §158.340). Included in this registration submission is a letter of support from Vulcan Chemicals. To support the other (minimum) data requirements, Bi-oxide has also included guideline data waiver requests (again in the 86-5 report format). These reports, with associated Guideline Reference Numbers are listed in Table 1.

Table 1. Reports submitted in support of a field use of sodium chlorite on wheat, barley, and oats.

Guideline Reference Number	Guideline Study Name (OPPTS No.)	MRID Number	Submitter	Status	Note
171-4	Magnitude of the Residue (OPPTS 860.1500)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request (1)
171-4	Nature of the Residue (OPPTS 860.1300)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
162-1	Soil Metabolism (OPPTS 835.3300)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
164-1	Soil Dissipation (OPPTS 835.6100)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
163-1	Sediment and Soil Adsorption/Desorption (OPPTS 835.1220)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
161-2	Photolysis (OPPTS 835.2210)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
161-1	Hydrolysis (OPPTS 835.2130)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
122-1	Nontarget Plant (OPPTS 850.4100)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
141-1; 141-2	Nontarget Pollinating Insects (OPPTS 850.3020; 3030; 3040)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
201-1; 202-1	Pesticide Drift Evaluation (OPPTS 840.1000)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
132-1; 133-3, 133-4	Post-Application Exposure (OPPTS 875.2000)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request

(1) Residue Analytical Method (Guideline Reference No. 171-4) would not be required if tolerance requirement is waived.

ChemReg requests that RD classify the active ingredient sodium chlorite and its use pattern on field treated small grain cereals as a reduced risk pesticide. This request is based on the facts that the material is an oxidizer and that the terminal residue is sodium chloride (table salt). In addition, the Agency (Antimicrobial Division) has already allowed for its use as a post harvest treatment on stored potatoes. Again for these reasons ChemReg believes that the field use of sodium chlorite on small cereal grains should fall in the reduced risk category. A sodium

chlorite based product would fit well into a fungicide program on a crop such as spring wheat and could serve as a substitute for a number of the current strobilurin (examples: azoxystrobin and pyraclostrobin) and triazole (examples: tebuconazole and propiconazole) based fungicides. A seasonal rotation using Biox Plus would be very beneficial for that strobilurin class since the registrants and the manufacturers actively promote resistance management strategies that include using different chemistries with different mechanisms of action. The use of Biox Plus could also result in the overall reduction in the use and the resulting residues of these fungicides. In addition the field use of Biox Plus should pose no hazard to the environment and non-target plants and animals.

Under the Registration Division Fee Schedule (PRIA), ChemReg believes that the Bioxide registration request for the reduced risk use of sodium chlorite and for the request for an exemption from the requirement of a tolerance qualifies as EPA Number R18. An R18 has a decision time of 20 months as per the 2006 Federal Fiscal Year. Again it is noted that this would not be the first crop use; this is based on the previous regulatory decision by the Agency (Brennis, Antimicrobial Division, August 5, 2003) in which the post-harvest use of chlorine dioxide, as generated from sodium chlorite, was approved on stored potatoes at rates of up to 400 ppm. In that decision a food residue tolerance was waived. Once the Agency assigns a PRIA Fee Code, Bi-oxide will request a waiver and will submit all of the necessary paperwork.

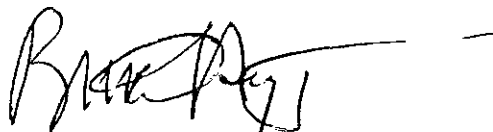
Attached with this cover letter are the following:

1. Agent authorization letter
2. Letter to EPA Summarizing the November 16, 2004 Pre-Registration Meeting
3. Copy of Pre-Registration Meeting Presentation
4. Application (EPA Form 8570-1)
5. CSF (basic)
6. Label (5 copies)
7. Transmittal Bibliography
8. Detailed Data Waiver (11) Reports (3 copies)
9. Executive Summary Report (3 copies)
10. Tolerance Petition (Exemption Request)
11. Letter of Authorization from Vulcan Chemicals
12. Notice of Filing for Federal Register
13. Computer disc containing copy of the Notice of Filing
14. Formulator's Exemption Statement (EPA Form 8570-27)

Office of Pesticide Programs  
Registration Division  
Carl Grable  
October 13, 2005  
Page 5 of 5

If you have any questions or need additional information, please contact me at (970) 392-1445 or (703) 927-8546 (cell phone).

Sincerely,

A handwritten signature in black ink, appearing to read 'Bruce D. Riggle', with a long horizontal line extending to the right.

Bruce D. Riggle, Ph.D.

Attachments

Volume 1 of 13 of Submission

**TRANSMITTAL DOCUMENT**

**NAME AND ADDRESS OF AGENT/SUBMITTER:**

ChemReg International, LLC  
Bruce D. Riggle, Ph.D.  
710 11<sup>th</sup> Avenue, Suite E-301  
Greeley, CO 80631-6404

**NAME AND ADDRESS OF REGISTRANT:**

Bi-oxide Crop Sciences LLC  
401 South Wall Street, Suite 103  
Calhoun, Georgia 30703

**REGULATORY ACTION:**

Submission of data waiver request reports to support a registration of Bi-oxide Crop Science LLC (Bi-oxide) 25% sodium chlorite end-use product for field use on wheat, barley, and oats and to support an exemption from the requirement of a tolerance for chlorite and chlorine dioxide on the appropriate raw agricultural commodities.

**TRANSMITTAL DATE:**

October 13, 2005

**LIST OF SUBMITTED REPORTS:**

<u>MRID</u> <u>NUMBER</u>	<u>VOLUME</u> <u>NUMBER</u>	<u>STUDY TITLE</u>	<u>EPA</u> <u>GUIDELINE NO.</u>
	1 of 13	TRANSMITTAL DOCUMENT	N/A
<b>46870101</b>	2 of 13	Executive Summary Review of Sodium Chlorite/Chlorine Dioxide For Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-1; August 3, 2005; 11 pages.	N/A

<b>46670102</b>	3 of 13	Waiver Request for Magnitude of the Residue in Plants and Livestock Animals for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-2; June 21, 2005; 233 pages.	171-2,3,4
<b>46670103</b>	4 of 13	Waiver Request for Nature of the Residue in Plants for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-3; June 21, 2005; 116 pages.	171-4
<b>46670104</b>	5 of 13	Waiver Request for Soil Dissipation for the Evaluation of Sodium Chlorite /Chlorine Dioxide For Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-4; August 1, 2005; 87 pages.	164-1
<b>46678801</b>	6 of 13	Waiver Request for Photodegradation in Water for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-5; August 2, 2005; 108 pages.	161-2
<b>46670106</b>	7 of 13	Waiver Request for Hydrolysis for the Evaluation of Sodium Chlorite/ Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-6; August 2, 2005; 41 pages.	161-1
<b>46670107</b>	8 of 13	Waiver Request for Metabolism in Aerobic Soil for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-7; August 2, 2005; 95 pages.	162-1

<b>46670108</b>	9 of 13	Waiver Request for Sediment and Soil Adsorption/Desorption for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-8; August 1, 2005; 74 pages.	163-1
<b>46670109</b>	10 of 13	Waiver Request for Re-Entry Exposure Protection Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Wheat, Barley, and Oats; Report No. CRGC-2005-9; July 13, 2005; 55 pages.	132-1, 133-3,4
<b>46670110</b>	11 of 13	Waiver Request for Spray Drift for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-10; August 1, 2005; 76 pages.	201-1, 202-1
<b>46670111</b>	12 of 13	Waiver Request for Non-Target Terrestrial Plant Requirements for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-11; July 19, 2005; 105 pages.	121-1, 122-1
<b>46670112</b>	13 of 13	Waiver Request for Non-Target Pollinating Insects and Honey Bees for the Evaluation of Sodium Chlorite /Chlorine Dioxide For Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-12; July 19, 2005; 65 pages.	141-1, 141-2

COMPANY AGENT:

Bruce D. Riggle  
NAME

Bruce D. Riggle  
SIGNATURE

Contact information: Bruce D. Riggle, Ph.D., phone 970-392-1445; cell 703-927-8546; riggle@chemreg.com.